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# California State Senate

## SENATE SELECT COMMITTEE ON INTERNATIONAL TRADE POLICY AND STATE LEGISLATION

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SENATOR  
**LIZ FIGUEROA**  
CHAIR



February 16, 2005

Ambassador Allgeier  
Acting United States Trade Representative  
1724 F Street NW  
Washington, DC 20006

Dear Ambassador Allgeier,

We are writing to express our concerns with readily identifiable ambiguities found in current and pending international trade agreement language. We believe that the vague nature of such language will infringe upon California's authority to provide quality and affordable health care services to our citizens.

Several components of U.S. obligations in the Australia-U.S. Free Trade Agreement (AUSFTA) and draft Free Trade Agreements (FTAs) conflict with California health policy. Legislation in California and in the Congress attempts to limit patent abuses, increase access to affordable drugs, and implement cost containment strategies. Trade negotiations, however, continue to promote the contrary by strengthening the resolve of patent holders and restraining the free market. We support government actions that encourage competition and achieve significant cost savings which include:

Imports and internet access to approved Canadian outlets that sell FDA-approved medicines.

Access to generics consistent with the options that the Food and Drug Administration and members of Congress have already proposed.

Preferred drug lists that favor cost-saving generics.

**Importing Drugs:** Since Canada and Europe have succeeded in keeping prices reasonable at a time when prescription drug prices have increased significantly in the U.S., the California legislature approved legislation to create a website for consumers to compare the prices of Canadian and U.S. pharmacies. Congress is also considering changes to current U.S. patent law, which allows patent holders to control the resale or importation of its product specifically to avoid U.S. consumer access to lower prices. Meanwhile, provisions of the AUSFTA and draft FTAs supersede congressional revision of those patent laws, creating international trade obligations where prior patent law language has been included in the agreements. California's interests, as well as those of the other states, have been best served when expanding competition through trade, not suppressing it. We urge you to exclude private import controls, which sustain the monopoly of highly priced prescription drug costs, from the language of future trade agreements.

**Access to generics:** The Medicare Modernization Act of 2003 regulates the legal retort of patent holders while encouraging generic manufacturers to file patent challenge applications. The McCain-Schumer Bill (S.812) further ensures that patent challenges do not promote anti-competitive business practices. These policies are consistent with Australia's new requirement that all patent extensions be in good faith. Separate and divergent from such regulatory efforts, are trade provisions in the U.S.-Australia, Central American, U.S.-Singapore, and U.S.-Morocco FTAs that all contain stanch limitations on government authority to allow the makers of generic drugs to challenge invalid patents and utilize data from prior clinical trials. California is a leader in biotechnology and surely recognizes the importance of patent-rights. However, our State cannot be a part to current trade rules that delay the production of generic drugs beyond a patent's reasonable, allotted expiration. These trade rules, shortsightedly negotiated by the U.S.T.R., impede access to affordable drugs for elderly, poor, and terminally ill patients, and further serve to undermine the work of state legislatures and the U.S. Congress in providing those most in need with state and federal relief.

**Preferred drug lists:** The AUSFTA undercuts the ability of states to consider cost effectiveness as a factor when deciding to grant preferred status to a drug. California's preferred drug list (PDL) promotes the most cost-effective and therapeutically advantageous products, while discouraging more expensive alternatives that are found to have no real benefit in regard to patient care. Any loss in bargaining power on behalf of the State will increase costs, thus limiting the overall effectiveness of California programs.

- 1) *Coverage* – The AUSFTA's Pharmaceutical Annex 2C covering "federal health care programs" defines such programs as those "in which the Party's federal health authorities made the decisions to which the annex applies." Given that California's Medi-Cal program operates under federal guidelines and that California must submit a State plan for federal approval in order to change or expand that program, it is certainly within the scope of reason to conclude that a closed-door, FTA dispute panel could potentially interpret the federal guidelines and approval process as a "decision," thereby making state programs "federal" and covered by the provisions of the trade agreement.

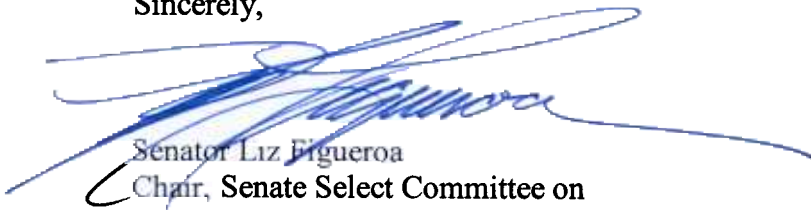
We implore the USTR to make a precise, internationally-accepted interpretation of Annex 2C known to the states and to develop language in concurrence with Australia that explicitly excludes state and local government programs. We believe that actions taken by the USTR in this regard will aid in the avoidance of future conflicts due to any misconstrued language under the current provisions.

- 2) *Principles* – Under the AUSFTA, "the need to promote timely and affordable access to innovative pharmaceuticals" is an apparent core-principle. However, for the State, while the term "affordable access" could apply to ensuring that California's program is affordable, the language also implies an assurance that individual consumers have access to each drug on the market, which is more affordable when every drug is listed. A dispute panel could interpret this imprecise definition to promote an overtly liberalized market; one that maximizes innovation in place of state interests to promote cost containment. Is the office of the USTR willing to clarify its interpretation of "affordable access" in this context?


- 3) *Independent review* – The AUSFTA requires the United States to provide an independent review panel for drug manufacturers whose applications to list a drug have been rejected. However, the AUSFTA fails to state whether this would be a case-by-case, federal review of state decisions regarding drug listings, what the panel's authority or responsibilities would include, and whether the panel would have enforcement powers to reject or change decisions made by the states. Further questions as to how states would gain representation at review panel proceedings and whether review panel findings will influence federal approval of state programs remain to be answered.

We thank you in advance for your prompt response to our questions and concerns. We would appreciate a written reply, along with copies of relevant documents that outline how you either have addressed or plan to address these concerns.

Sincerely,



Senator Liz Figueroa  
Chair, Senate Select Committee on  
International Trade Policy and State Legislation



Senator Sheila Kuehl  
Vice Chair, Senate Select Committee on  
International Trade Policy and State Legislation